Med Trib 19

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Treatment With Ultrasound Blocks Spermatogenesis

Medical Tribune Report

Ultrasound method suppressed spermatogenesis in first five patients after 20-minute treatment. Volunteer places testes in water-filled cup. Fluid acts as coupling agent for vibrations from ultrasonic device.

LAS VEGAS—A pilot clinical study of ultrasound for the suppression of spermatogenesis shows it to be both safe and effective, a University of Missouri scientist told the 32nd annual meeting of the American Fertility Society here.

While the optimum dosage schedule has yet to be worked out, the method has advantages that could make it a widely accepted form of male contraception, said M. S. Fahim, Ph.D., Professor and Chief of Reproductive Biology in the Department of Obstetrics and Gynecology, University of Missouri Medical Center, Columbia, Mo.

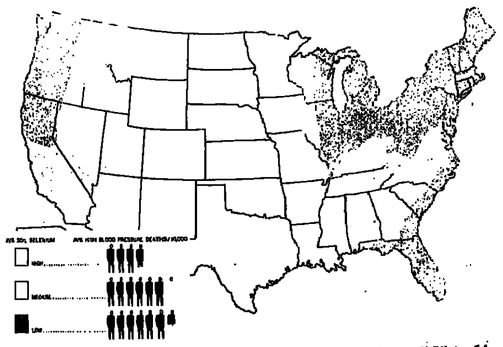
The main advantages are its noninvasive and non-pharmacologic nature, he said.

Although it effectively suppresses spermatogenesis, there are no side effects, no pain, and in the proper dosage it may be naturally reversible.

In addition, treatment usually increases the patient's libido, and most

Continued on page 21

Soil Selenium and High Blood Pressure Deaths



Death rates from hypertension-related disease among people aged 55 to 64 are as much as 300% higher in U.S. areas where the soil is low in selenium than in selenium-rich areas, a Cleveland Clinic study indicates. See story below.

Heart/Stroke Deaths Linked To Low Intake of Selenium

By JOHN HENAHAN
Special Tribune Correspondent

ANAHEIM, CALIF.—New epidemiological studies linking low environmental and dietary levels of selenium and copper to hypertension-related disease and cancer were reported in a series of papers presented here at the 60th annual meeting of the Federation of American Societies for Experimental Biology (FASEB).

Americans who live in areas where selenium levels are low are up to three times more likely to die from heart attack, strokes and other diseases related to high blood pressure than their countrymen in high selenium areas, according to a survey carried out by Raymond J. Shamberger, Ph.D., and Dr. Charles E. Willis of the Cleveland Clinic. Selenium is a trace metal found in soil, plants and water, and is required in small amounts for proper body functioning.

After comparing the selenium con-

Continued on page 13

100% Remission in Leukemia Achieved by Chemotherapy

By NATHAN HORWITZ
Medical Tribune Staff

PHILADELPHIA—The use of combination chemotherapy, including an antitumor antibiotic, has achieved 100% remission in a preliminary series of adult patients with acute lymphocytic leukemia, an Indiana University team has reported.

Complete remission occurred in most cases within two weeks of the start of therapy, and most patients have remained symptom-free for a median

Continued on page 13

From La Tribune Médicale

In Suffering, Terminal Patients:

53% of French GPs Would Consider Passive Euthanasia

By JEAN-MICHEL JOLY AND MICHEL NERON

Recently, LA TRIBUNE MEDICALE, the French edition of MEDICAL TRIBUNE, sponsored an extensive poll of the attitudes of French general practitioners towards euthanasia. Following are the results, with commentaries by the analysts.

Recent legislation liberalizing abortion has left euthanasia an outstanding medical problem. During these last months, a sequence of events has sensitized public opinion: the Hammerli case in Switzerland, Franco's agony, and, above all, the Karen Ann Quinlan case have focused attention on all aspects of the problem—medical, economic, judicial, humane and religious.

What is the opinion of the general practitioner in France today? This fundamental question has never been pursued in a scientific manner. Consequently, at the request of LA TRIBUNE MEDICALE, the Société Francaise d'Etude et de Sondages (SOFRES), France's equivalent of George Gallop Associates, polled a representative sample of general practitioners. The intention was not to cover the entire issue but to reveal, in the four questions posed, an accurate, if inevitably simplified, picture of French medical opinion in November, 1975.

Coming Next Week

MEDICAL TRIBUNE will publish the results of a comparable poll of American family physicians' attitudes towards this sensitive and timely issue.

Have you had a terminally ill patient ask you to cut short his suffering?

	TOTAL	Age of Physician: 35 years and less	36 to 50 years	Over 50 years
Yes	53%	36%	62%	60%
No	47%	64%	38%	40%

Over half the doctors had been confronted with a patient who explicitly requested abrogation of his suffering. One can therefore say with certainty that the demand for euthanasia exists, since it has been encountered by 53% of the doctors at least once during their practice. This proportion reaches 60% among doctors over 35 years old, in practice for at least five years.

This observation seems inconsistent with the position of certain hospital authorities to whom euthanasia could in no way be justified in view of the present arsenal of pain-killing drugs.

Can the progress of medical technique avert the individual's claim, when facing his doctor, to his "right to death"?

Continued on page 12

Medical Devices Becoming Focus Of Malpractice Suits and Legislation

By ANASTASIA TOUFEXIS
Medical Tribune Staff

NEW YORK—"The slogan used to be 'Support the legal profession, send your son to *medical* school.' Perhaps it should be expanded to 'Go into the medical device *manufacturing* field.' "

This observation made by cardiovascular surgeon Harold Laufman, president of the Association for the Advancement of Medical Instrumentation, at a national conference on medical device liability sponsored by the Public Liability Institute of New York University's Center for Safety, reflects the concern, voiced by many physicians, that medical devices and equipment are increasingly becoming the focus of malpractice suits and legislative regulation. The physician is virtually caught in the middle.

Physicians Worried

He either gets sued by the patient or himself sues the manufacturer. And proposed federal regulation has provoked fears that development of new devices and modification of existing ones will be stifled. In short, some physicians are worried that their ability to provide patients with the very best care at reasonable cost is being compromised.

It is a simple rule. The more complex the device, the greater the possibility something can go wrong. And as things go wrong with today's highly sophisticated and complex medical tools, patients increasingly sue.

The patient, says Irwin Birnbaum, governor of the Association of Trial Lawyers of America and adjunct professor of law at Syracuse University, awakened by consumerism and the publicity surrounding the current malpractice crisis, is realizing he can sue not only his doctor and the hospital but the supplier of the pacemaker implanted in his chest, the maker of the prosthetic joint replacement in his hip and the company that provided the needles or support equipment used during surgery.

As a corollary, third party suits have also multiplied, says Mr. Birnbaum, as plaintiffs and defendants bring third parties into disputes and file cross claims. The patient, already suing his doctor, files against the hospital for contributory negligence. And the doctor-defendant sues the manufacturer, claiming he was supplied with defective equipment.

However, according to a 1970 report prepared by HEW, at least two-thirds of device "misadventures" are the result not of faulty design or manufacture but of improper use and negligent maintenance.

Dr. Richard Johns of the biomedical engineering department of Johns Hopkins Medical Hospital, says, "Many of these problems are not detected or even suspected. For example, non-sterile compressed gas used to power some of these devices can leak out of a crack in an exhaust line."

Dr. Johns attributes unsafe or ineffective use of properly designed and manufactured devices to a number of factors. "Hospitals and health care professionals traditionally have not regarded medical care as a high technology industry," he says. "It's crept up on them.

"Hospital engineering has also in the past been facilities oriented. It has not been geared to high technology devices and systems, which are becoming increasingly complex and increasingly prevalent. And finally, you tend to have the highest staff turnover in areas where technology is most evident—operating rooms, ICU's and recovery rooms. These are high pressue areas."

Manufacturer Liable

Nevertheless, Mr. Birnbaum sees the deck weighted against the manufacturer. Standards of liability are far stricter for the manufacturer than for the physician, he says. A doctor is judged by intraprofessional standards, by the generally accepted standard of care. Even then, he claims, a physician can win his case if he can prove that a substantial minority of physicians, or physicians in his locality, follow the same procedures.

The manufacturer, on the other hand, is held liable for negligence if the product was defectively designed or made. And a company can be sued if the physician misuses the product or fails to follow the patient. This last makes recalls of faulty equipment difficult and sometimes impossible. Understandably, however, medical device companies are reluctant to file suit against physicians.

Furthermore, says Mr. Birnbaum, manufacturers have been alarmed by a discernible trend to what is called "no-fault" or "enterprise" liability.

Federal Regulation Coming

Decisions have been handed down in which companies were exonerated of negligence in either the design or manufacture of a device but were nevertheless held culpable because the product failed to meet the "reasonable expectations of the consumer."

Mr. Birnbaum also cites a New Jersey case in which the court refused to accept a jury judgment of not guilty when a patient failed to prove culpability on the part of his surgeon, the device manufacturer or the supplier. The judge ruled that the patient was unconscious and obviously not responsible for the injury.

"The costs of no-fault liability will be astronomical, particularly for the manufacturer," Mr. Birnbaum predicts.

The manufacturers of medical devices will shortly be subject to federal regulation. On March 9, the House overwhelmingly approved bill #11124, formally titled "Medical Devices Amendments of 1976," which amends the Food, Drug and Cosmetic Act. Senate-House conferences are expected to iron out differences between this bill and Senate bill 510 passed nearly a year ago.

In broadest terms, the final bill will classify devices, outline procedures for premarket approval and human testing, and set performance standards for safety and efficacy.

"Medical device product testing will be analogous to the drug testing experience," says doctor-lawyer Richard J. Brown, director of medical research planning at Hoffmann-LaRoche.

He expects problems in determining
Continued on page 6

index

CLINICAL NEWS NOTE: *"Recently, we found that ultrasound was more effective as a suppressant of spermatogenesis at 38°C in male rats than hot water (60°C), infrared and microwave. This is due to its combined effect of heat and mechanics. This combined effect could cause an ion exchange between the fluid in the seminiferous tubules and rete testis creating an environment not suitable for spermatogenesis. . . . Five human patients with carcinoma of the prostrate, who are to undergo orchiectomy, were treated with 1 watt/cm² for fifteen minutes while sitting in a special chair. They experienced no pain or other side effects. Histological studies indicate that ultrasound affects spermatogenesis in man. This pilot study suggests the possibility of reversible and irreversible, non-surgical, non-pharmacological sterilization in human males."* (M. S. Fahim, Ph.D., University of Missouri-Columbia Medical School. See page 1.)

Medicine: 1, 3, 7, 17

Sperm production is suppressed by ultrasound therapy 1
Heart/stroke deaths linked to low selenium intake 1
Adult leukemia remissions 100% on combined chemotherapy 1
Passive euthanasia in terminal patients considered by 53% of French GPs.....1
Medical devices becoming the focus of malpractice suits and legislation 3
Prostatic cancer: radioactive iodine implants favored as treatment 3
Ibuprofen relieves pain of dental surgery 7

feature index

Editorial Capsules 7
Editorials 11
Letters to Tribune 17
Eliot Janeway 13
Epigram 17
Medicine on Stamps 17
One Man...and Medicine 17
Immateria Medica 23

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Radioactive Iodine Implants Favored in Treatment of Early Prostatic Cancer

Medical Tribune Report

MORGANTOWN, W. VA.—Implantation of radioactive iodine seeds in the prostate gland is the best treatment available for early stage prostatic cancer, according to a urology-radiology team at West Virginia Medical Center.

The technique has decided advantages over radical prostatectomy or external radiation in patients whose disease is localized to the prostate gland, that is, Stage A and B carcinoma, say Dr. Stanley Kandzari, associate professor of urology, and Dr. P. R. Reddi, director of the division of radiation therapy.

Nine patients have been treated with radioactive iodine implants at the Center so far. Follow-up biopsies on two patients, at six and nine months postop, have been negative.

The technique, which was developed at Memorial Hospital in New York City, involves dissection of the pelvic lymph nodes and implantation of I-125 pellets into the prostate gland. "About 20 to 30 seeds are implanted according to the size of the prostate gland," says Dr. Reddi.

Special Gun

The pellets are discharged into the gland by a special gun which fits over hollow stainless steel needles that are inserted into the tissue at varying positions and depths. Following the implant of the pellets, the needles are withdrawn and the incision closed.

Radioactive iodine, rather than gold or radon, is used because with its half-life of 60 days, it has a slow decay and
Continued on page 13

I-125 seeds are shot into prostate gland by special gun which fits over tissue-implanted hollow needles.

Tested by time and experience in the treatment of MBD

1962

"…a considerable decrease of hyperactivity…."[1]
Knobel, 1962

Over a decade of controlled studies and clinical experience has shown the effectiveness of Ritalin in reducing the hyperactivity,[1-3] distractibility,[1,4,5] and disorganized behavior[1-8] in the MBD child.

By lessening the effects of motor and attentional disorders, Ritalin can help the MBD child to better focus his attention on meaningful stimuli and thus can often improve cognition and promote learning.[8,9]

And side effects—insomnia and appetite loss—with Ritalin have occurred less frequently than with dextroamphetamine.[10,11]

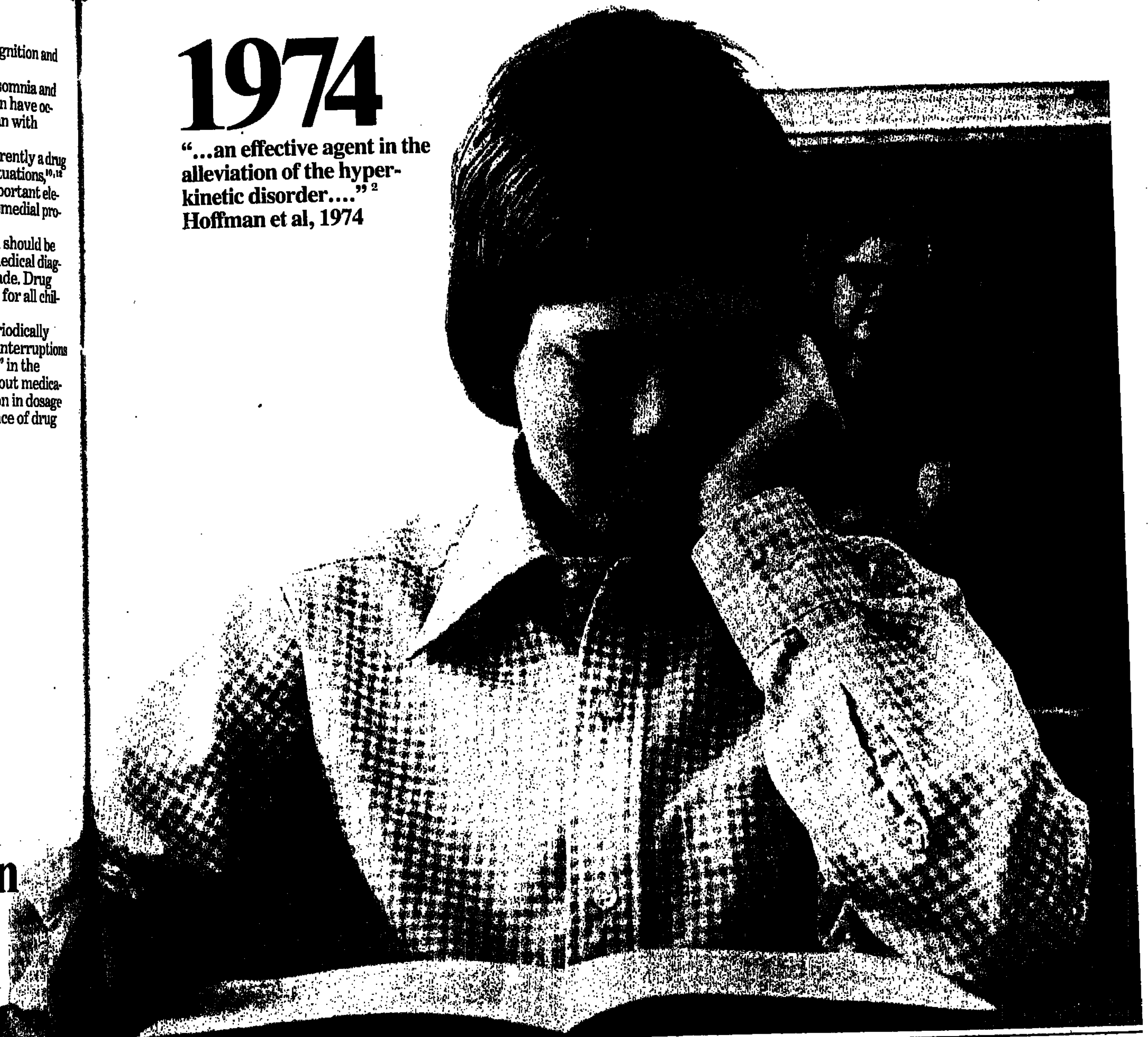
Indeed, Ritalin is currently a drug of choice in many MBD situations,[9,12] and can prove to be an important element in many complete remedial programs for MBD.

Therapy with Ritalin should be undertaken only after a medical diagnosis of MBD has been made. Drug treatment is not indicated for all children with MBD.

Dosage should be periodically interrupted. Often, these interruptions reveal some "stabilization" in the child's behavior even without medication, permitting a reduction in dosage and eventual discontinuance of drug therapy.

1974

"…an effective agent in the alleviation of the hyperkinetic disorder…."[2]
Hoffman et al, 1974



Ritalin®
(methylphenidate)
Only when medication is indicated

Ritalin® hydrochloride ©
(methylphenidate hydrochloride)

TABLETS

INDICATION
Minimal Brain Dysfunction in Children—as adjunctive therapy to other remedial measures (psychological, educational, social)
Special Diagnostic Considerations
Specific etiology of Minimal Brain Dysfunction (MBD) is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but of special psychological, educational, and social resources.
Characteristics commonly reported include: chronic history of short attention span, distractibility, emotional lability, impulsivity, and moderate to severe hyperactivity; minor neurological signs and abnormal EEG. Learning may or may not be impaired. The diagnosis of MBD must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics.
Drug treatment is not indicated for all children with MBD. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is generally necessary. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms.

CONTRAINDICATIONS
Marked anxiety, tension, and agitation, since Ritalin may aggravate these symptoms. Also contraindicated in patients known to be hypersensitive to the drug and in patients with glaucoma.

WARNINGS
Ritalin should not be used in children under six years, since safety and efficacy in this age group have not been established.
Sufficient data on safety and efficacy of long-term use of Ritalin in children with minimal brain dysfunction are not yet available. Although a causal relationship has not been established, suppression of growth (ie, weight gain and/or height) has been reported with long-term use of stimulants in children. Therefore, children requiring long-term therapy should be carefully monitored.
Ritalin should not be used for severe depression of either exogenous or endogenous origin or for the prevention of normal fatigue states.
Ritalin may lower the convulsive threshold in patients with or without prior seizures; with or without prior EEG abnormalities, even in absence of seizures. Safe concomitant use of anticonvulsants and Ritalin has not been established. If seizures occur, Ritalin should be discontinued.
Use cautiously in patients with hypertension. Blood pressure should be monitored at appropriate intervals in all patients taking Ritalin, especially those with hypertension.
Drug Interactions
Ritalin may decrease the hypotensive effect of guanethidine. Use cautiously with pressor agents and MAO inhibitors. Ritalin may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (phenobarbital, diphenylhydantoin, primidone), phenylbutazone, and tricyclic antidepressants (imipramine, desipramine). Downward dosage adjustments of these drugs may be required when given concomitantly with Ritalin.
Usage in Pregnancy
Adequate animal reproduction studies to establish safe use of Ritalin during pregnancy have not been conducted. Therefore, until more information is available, Ritalin should not be prescribed for women of childbearing age unless, in the opinion of the physician, the potential benefits outweigh the possible risks.

Drug Dependence
Ritalin should be given cautiously to emotionally unstable patients, such as those with a history of drug dependence or alcoholism, because such patients may increase dosage on their own initiative. Chronically abusive use can lead to marked tolerance and psychic dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during drug withdrawal, since severe depression as well as the effects of chronic overactivity can be unmasked. Long-term follow-up may be required because of the patient's basic personality disturbances.

PRECAUTIONS
Patients with an element of agitation may react adversely; discontinue therapy if necessary.
Periodic CBC, differential, and platelet counts are advised during prolonged therapy.

ADVERSE REACTIONS
Nervousness and insomnia are the most common adverse reactions but are usually controlled by reducing dosage and omitting the drug in the afternoon or evening. Other reactions include: hypersensitivity (including skin rash, urticaria, fever, arthralgia, exfoliative dermatitis, erythema multiforme with histopathological findings of necrotizing vasculitis, and thrombocytopenic purpura); anorexia; nausea; dizziness; palpitations; headache; dyskinesia; drowsiness; blood pressure and pulse changes, both up and down; tachycardia; angina; cardiac arrhythmia; abdominal pain; weight loss during prolonged therapy. Toxic psychosis has been reported. Although a definite causal relationship has not been established, the following have been reported in patients taking this drug: leukopenia and/or anemia; a few instances of scalp hair loss.
In children, loss of appetite, abdominal pain, weight loss during prolonged therapy, insomnia, and tachycardia may occur more frequently; however, any of the other adverse reactions listed above may also occur.

DOSAGE AND ADMINISTRATION
Children with Minimal Brain Dysfunction (6 years and over)
Start with small doses (eg, 5 mg before breakfast and lunch) with gradual increments of 5 to 10 mg weekly. Daily dosage above 60 mg is not recommended. If improvement is not observed after appropriate dosage adjustment over a one-month period, the drug should be discontinued.
If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage, or, if necessary, discontinue the drug.
Ritalin should be periodically discontinued to assess the child's condition. Improvement may be sustained when the drug is either temporarily or permanently discontinued.
Drug treatment should not and need not be indefinite and usually may be discontinued after puberty.

HOW SUPPLIED
Tablets, 20 mg (peach, scored); bottles of 100 and 1000.
Tablets, 10 mg (pale green, scored); bottles of 100, 500, 1000 and Accu-pak® blister units of 100.
Tablets, 5 mg (pale yellow); bottles of 100, 500, and 1000.
Consult complete product literature before prescribing.

CIBA Pharmaceutical Company
Division of CIBA-GEIGY Corporation
Summit, New Jersey 07901

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C I B A

Malpractice Suits Now Focusing on Medical Devices

Continued from page 3

what constitutes substantial evidence, adequate and controlled study, expert testimony, benefit-risk ratios, clinical vs. statistical significance, and informed consent. "Efficacy is not as simple as 'does this product work?' " he declares. He also foresees difficulties in balancing full disclosure directives with trade secret confidentiality.

Then there is the matter of record-keeping. "You must keep files on protocols, reports, analyses, patient case histories, adverse reactions and data reports," he notes.

Physicians already in an uncomfortable adversary position with the public and the manufacturer, fear that the new rules may delay innovations and make delivery of quality care more difficult and expensive.

Legislation Defective

Dr. Laufman cites at least five major defects in the present Senate bill: device classification will be made by administrators, not panels of scientific experts; existing standards organizations will have no voice in setting performance and development standards; experimental use of devices will require approval by a federal agency; informed consent guidelines will remain as presently set; and the manufacturer will be judged not by the state of the art at the time the device was designed but by current standards—in other words, retroactive liability.

"If we don't get a broader, less legalistic and more common sense approach which tolerates the inevitable imperfections, then eventually we're going to reach the point where patients will sue us simply for getting sick," Dr. Laufman declares.

However, Dr. Laufman emphasizes that "we do need device legislation. And actually the House bill is pretty good. But there's more to regulation and standards than a chained-to-the-bench rigidity."

Dr. William F. Donaldson, immediate past president of the American Academy of Orthopaedic Surgeons, agrees. "We are not seeking a status quo," he stresses. "What we want is the ability to improve and develop new devices for the better care of our patients.

"We are just beginning a most productive era in the development of new materials such as ceramics and cintered metals, of new designs for total joint replacement, of improved methods of fracture fixation, of new methods for stimulating fracture healing, and of new materials for artificial ligaments," he says.

Stifling Innovation?

"Our concern is that inappropriate measures, overregulation, the bureaucratic maze will result in the stifling of innovation and in a significant increase in cost for development of new devices and the modification of existing implants. This would lead to poorer, more expensive care for our patients."

Dr. Donaldson points out that significant progress in scoliosis or total joint implantations "could well have been thwarted or overly delayed in clinical application" had the new rules been in effect.

"There is no animal model for scoliosis," he explains. "Instrumentation had to be developed using anatomic models, but its application to the clinical situation required its use in the only population who develops it—the human."

Total hip replacements "opened new horizons for the design, development and the trial of new implants for other damaged joints," he continues. Associated with these new applications are new design, wear and fixation problems.

"For example, the knee joint has a much more complicated arc of motion than does the hip joint," he says. "As a result, there is less tolerance for error in the insertion of the component parts."

Patient Protection

Physicians are also concerned that "devices will be faulted when, in fact, the problem is not attributable to the device, but rather to other circumstances surrounding its use," says Dr. Donaldson. For example, an internal fixation device used to immobilize a fracture may break due to stresses placed on the device by the fracture failing to unite. Or a device inserted only to immobilize a fracture fails when the patient bears weight on the limb.

The consensus? Patients should be protected. But they should also benefit from technological advances.

EDITORIAL CAPSULES

... brief summaries of editorials or comments in current merical and scientific journals.

Health Statistician

"The emergence of the cost/effectiveness concept places a heavy responsibility on the health statistician, whose role it is to provide the factual input. The outcome will be a much more serious approach to health programme composition and a much more critical evaluation of achievements and failures. In short, the difficult problem[s] ...must be faced and solved." *(Article, Forrest H. Linder, WHO Chronicle 30:58, Feb., 1976)*

CHD: Differences Abroad

"...Workers in Edinburgh and Stockholm lately conducted a study of risk factors for coronary heart-disease in 40-year-old men which throws some light on the relative importance of risk factors. Community surveys have disclosed a greater incidence of C.H.D. in Edinburgh than in Stockholm and deaths from C.H.D. in younger men (less than 60 years) are about 2.5 times more common in Edinburgh. Men aged 40 years were randomly selected in the two cities and were invited to participate in the study, with actual participation-rates of 89% in Stockholm and 52% in Edinburgh (or 70% of those who replied).

". . . The result which immediately claims attention is the similarity between cholesterol values in the two cities (249 mg/dl in Edinburgh and 254 mg/dl in Stockholm). One may well ask why there should then be such a striking difference in C.H.D. frequency between those two populations. . . .

"...Smoking and raised blood-pressure are well-established risk factors for C.H.D. and they differed substantially between the two populations. In Stockholm 57% of subjects were non-smokers compared with 36% in Edinburgh. Unfortunately and surprisingly, the term non-smokers includes ex-smokers and pipe or cigar smokers The fact that cigarette smokers in both cities smoked the same number of cigarettes is irrelevant. It is possible that the difference between the proportions of 'never smoked' could be even more striking and of considerable importance. In Stockholm, the mean systolic blood-pressure was significantly lower and there were significantly more men with low systolic blood-pressure. Edinburgh had significantly more men with raised serum triglycerides and insulin. The data were also examined for the number of men from each city appearing in the highest quintile (20%) of each risk factor. The number of men in four or more of the high risk "tails" was somewhat greater in Edinburgh, but the most striking finding was the difference between the two cities in the proportion of men with *no* high-value risk factors—34% of the Stockholm men and only 15% of the Edinburgh men...." *(Editorial, The Lancet 1:402, Feb. 21, 1976)*

Low Dosage Ibuprofen Relieves Dental Pain

Medical Tribune Report

WASHINGTON, D.C.—The antiarthritic drug ibuprofen in low dosage (200 mg tablet) has proved as effective as two standard tablets of aspirin for relieving pain after dental surgery, according to findings of a study made here at the Georgetown University School of Medicine and Dentistry.

Spokesmen for The Upjohn Company, manufacturers of ibuprofen, told MEDICAL TRIBUNE that extensive testing of the agent for short-term analgesia is being done under the Investigational New Drug procedure. The agent is now approved for chronic symptomatic treatment of rheumatoid arthritis and osteoarthritis.

A total of 192 patients who had undergone removal of impacted or embedded teeth took part in the investigational drug trial, which was conducted by Stephen A. Cooper, D.M.D., Ph.D., Assistant Professor of Oral Surgery and Pharmacology, and Stephen Needle, D.D.S.

Patients were divided into five groups and assigned to receive single doses of a placebo, 325 mg aspirin (one tablet), 650 mg aspirin, 200 mg ibuprofen, or 400 mg ibuprofen.

The smaller dose of ibuprofen produced an effect equal to that of two aspirin tablets while the larger dose yielded results "significantly better" than those seen with 650 mg aspirin, Dr. Cooper found.

The antiarthritic agent reached peak effectiveness during the third hour after administration, and its effects were longer lasting than those of aspirin.

New Anti-inflammatory Agent

► Naproxen, a non-steroidal and anti-inflammatory agent developed by Syntex Laboratories, has been approved by the FDA for the treatment of rheumatoid arthritis.

Chemically unrelated to either the salicylates or to corticosteroid hormones, the drug has been shown in clinical trials here and abroad to reduce such manifestations of rheumatoid arthritis as joint swelling, pain, and duration of morning stiffness.

on average, sleep within 17 minutes that lasts for 7 to 8 hours with fewer nighttime awakenings[1] proved in patients with insomnia in 8 sleep research laboratory studies

for patients who need it, continued effectiveness over 28 nights[2,3] prolonged medication for insomnia is generally not necessary; should it be, the only available sleep agent proved objectively to be effective longer than two weeks is Dalmane (flurazepam HCl)

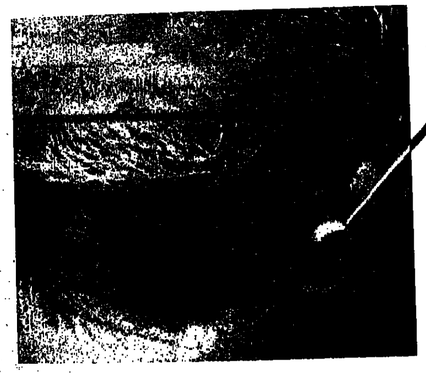
proven effectiveness in elderly patients with verified insomnia[4] the greater the degree of insomnia, the greater the objective improvement with Dalmane 15 mg administered for 7 nights *h.s.*—15 mg is the recommended initial dosage for elderly and debilitated to help preclude oversedation, dizziness or ataxia

a full night's sleep with a single *h.s.* dose[1-8] patients fall asleep faster, awaken less often during the night, sleep longer without repeating dosage

well tolerated, seldom causes morning "hang-over"[1] Dalmane is a distinctive benzodiazepine specifically indicated for sleep with well-documented safety and low incidence of morning "hang-over"

more documentation from the sleep research laboratory than any other agent for insomnia[1-8] polysomnographic techniques provide the most objective measurement of effectiveness possible

relative safety extending even to patients on chronic warfarin therapy[1,9] no unacceptable fluctuation in prothrombin time has been reported with Dalmane



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The Frightening Pelvic Examination

UNDER THE RUBRIC of Perspective, a remarkable bit of writing with the title, "The Pelvic Examination: A View from the Other End of the Table," appeared in the October, 1975, issue of *The Annals of Internal Medicine*. Its author is Dr. Joni Magee, who is in the department of obstetrics and gynecology at the Jefferson Medical College of Thomas Jefferson University in Philadelphia. Since she is a woman physican, the view she gives, although primarily from on the table, "positioned and draped in the usual manner, legs in stirrup, sheet over my knees so I couldn't see over them, my perineum exposed to whatever breeze might have been stirring," she also writes from the viewpoint of the physician, "sitting down there between her legs where she [the patient] can't see you getting ready to apply all sorts of unknown tortures."

The perspective ought to be read by every medical student, every primary physician including the internist, every obstetrician and gynecologist—in short, at some time, by every physician. What Dr. Magee writes is a message to the physician—and truly beyond the matter of the pelvic exam—how to be human and humane. But her area of emphasis is the pelvic exam and what she says should be carefully studied. She adds that "...doctors only learn how patients feel by being patients or listening to them. All patients who get pelvic examinations are women, so open your ears, men. You'll never learn from personal experience."

As to personal experience, she mentions having heard of a very progressive medical school, which she hopes is not apocryphal, "where every male student is placed in stirrups and a strange female physician comes in, squeezes his balls, and leaves without saying a word." Even that might not teach the male physician to introduce himself first to the patient while she is still seated and preferably dressed, to communicate while doing the pelvic exam, to say in advance just what he is doing, to tell her how to relax, to explain what the speculum is, to warm it in water before insertion, etc. But reading Dr. Magee's perspective is guaranteed to do so.

Euthanasia and the Terminally Ill

THIS ISSUE OF MEDICAL TRIBUNE contains the reports of a poll by our sister publication, LA TRIBUNE MEDICALE, of a representative sample of French general practitioners on the subject to euthanasia (see pages 1, 12). As the French reporters note, recently "a sequence of events has sensitized public opinion: the Hammerli case in Switzerland, Franco's agony, and, above all, the Karen Ann Quinlan case have focused attention on all aspects of the problem—medical, economic, judicial, humane, and religious."

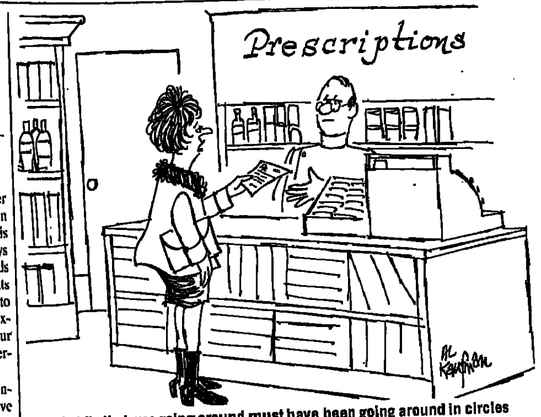
Of course, the focusing of attention by the public has also focused the attention of physicians once again. It is of interest to see the varied experiences and varied views of the French physicians, depending on their age, in response to the questions asked in the poll. It is not surprising that more of the older physicians than the younger have had the experience of being asked by a terminally ill patient to cut short his suffering. By chance alone this is more likely to be so, since the older physician has practiced longer and seen more terminally ill patients.

The greatest percentage of the physicians, whatever their age, were against *active* euthanasia in the case of the terminal patient in unbearable pain, 83% voting in this fashion, although the figure for the physicians over 50 who opted for that viewpoint amounted to 73%. As to passive euthanasia, 53% were in favor of it, the figure being 55% for those physicians 35 years old and younger, 41% for those 36-50, and 67% for those over 50. Our French colleagues observe that, "Practitioners approaching the last stage of their careers do not lock themselves into 'semantic subtleties.' To speak of death is also, in a way, to project their own anguish." That may be so, but it is at least equally likely that the oldest practitioners have more often experienced the terminally ill patients whose suffering seems unbearable, and as these experiences have multiplied, have come to look with favor on passive euthanasia—"an omission of action which hastens the end."

Next week's issue of MEDICAL TRIBUNE will contain the results of an identical poll conducted among American primary care physicians. It will be of interest to compare the French and American data.

Chemotherapy of Adult Leukemia

CLINICAL QUOTE: *"Although we have treated only nine patients with our present regimen, it is highly encouraging that the worst survival (13 months) was better than the median survival of our previous regimens.... Complete remission was defined as a normal CBC and a normal cellular BM, with 0-5% lymphoblasts and fewer than 40% lymphocytic elements in the marrow, and no signs or symptoms of leukemia. Duration of complete remission was defined as the interval from initial complete remission to relapse, either hematological or CNS with meningeal leukemia. Most patients were in complete remission within two weeks."* (Dr. Lawrence H. Einhorn, Associate Professor of Medicine, Indiana University Medical School, at the American College of Physicians meeting. See p. 1.)



"That flu that was going around must have been going around in circles because my husband got it again."

LETTERS TO TRIBUNE

Jello Legal Problems

When I saw the article on the EEG's on a bowl of lime jello [MT, Mar. 3], I was struck by two misgivings. First, if this jello is indeed not legally dead; then you will have difficulties in disposing of it. Secondly, if you cannot dispose of it, with the beautiful brain waves obtained, it is possible that this jello might be accepted into law school, might end up holding a high office and become engaged in making rules and regulations for the conduct of medicine.

I hope you have been able to destroy this threat to our security.

JAS. WM. DICKEY, JR., M.D.
Fort Lauderdale, Fla.

On PSRO

Note [MT, Feb. 18 and 25] that the government argues [in the case of the Association of American Physicians and Surgeons challenging the constitutionality of the PSRO law] that under Medicare—and therefore under any National Health Insurance scheme—patients have *no* constitutional right to obtain care from a physician of their choice.

PSRO has essentially one admission review provision—and the same loss of privacy of will.

Is there no limit to their arrogance?

F. M. BALL, M.D.
Charleston, S.C.

Why Silence

In his January 21, 1976 editorial, Dr. Sackler called attention to "the resounding silence" of the consumers to the crises brought on by the skyrocketing costs of professional liability insurance. It occurred to me that other voices—of comprehensive health care agencies (some, by law, consisting of 51% consumers), the health care "engineers," some of our colleagues in administrative and educational positions—usually loud and articulate in their condemnation of the inefficiency of "the cottage industry," "wasteful" hospitalization, and duplication of medical facilities, are similarly mute having little to say about the five-figure premiums for physicians and the seven-figure premiums for hospitals.

They must know that they will drive up the costs of medical care or drive physicians and hospitals out of business. They must realize that liability insurance protects not only the physician and the hospital, but also the patient.

Why the silence? "They have mouths and speak not."

Why?

MARCUS J. SMITH, M.D.
Santa Fe, N.M.

Jog-jogging Along

If there is a joke anywhere in jogging, it certainly must be on Dr. Grossman [Letters, MT, Apr. 14]. I am sure he knows that even the minimum requirements for cardiopulmonary fitness training cannot be met in the way he suggests.

"Aimless and useless" jogging has as some of its goals the following: Improved general fitness; enhanced oxygen transport; increased coronary perfusion; reduced resting pulse; decreased plasma lipid concentrations; increased caloric expenditure leading to more ideal body weight; and greater sense of well-being. The result is enhancement of the quality of life, an increase in longevity because of a lessened risk of catastrophic arterial events, especially myocardial infarction. If these aren't worthwhile goals, I don't know where to look for better ones.

As physicians, we are able to recommend to our patients things that will help them in many ways. Let's not deny them the opportunity of living longer and feeling better. The values of regular exercise of the proper kind, tailored to the requirements of the individual, are not in doubt any longer. Let's become knowledgeable about endurance training, be examples to our patients, and give them the chance to share in the many benefits that can accrue to them.

JOHN F. MOE, M.D.
Indianapolis, Ind.

53% of French GPs Would Consider Passive Euthanasia

Faced with a terminal patient whose suffering seems unbearable, can one, in your opinion, consider...

	TOTAL	Age of Physician: 35 years and less	36 to 50 years	Over 50 years
Passive euthanasia				
Yes	53%	55%	41%	67%
No	36%	33%	43%	30%
No Comment	11%	12%	16%	3%
Active euthanasia				
Yes	13%	6%	8%	27%
No	83%	85%	89%	73%
No Comment	4%	9%	3%	—

Continued from page 1

Passive euthanasia was defined for physicians by the investigators as "an omission of action which hastens the end." This definition was intentionally broad in order to include all possible situations and not to create a leading question.

It is conceivable that among the 11% who did not declare themselves, some had in fact considered this definition as being too encompassing in comparison to their more restrictive concepts, while others took refuge in "No comment" in order to evade a problem that perhaps "disturbed" them.

More than half the physicians considered resorting to passive euthanasia. On the surface, this score seems surprising. Among doctors over 50 years old, the question elicited two positive responses out of three. However, doctors in the fastest growing stratum of professional activity (35 to 50 years old) were the least favorable towards euthanasia (41%) and included the largest proportion to take a no-comment stand (16%). On the other hand, a comparison of cross-sections by age indicates that young doctors, who generally have not often been confronted with the reality of the problem, adopt a position generally more favorable to euthanasia than their immediate elders (36-50 years old), who are definitely more reticent.

Practitioners approaching the last stage of their careers do not lock themselves into "semantic subtleties." To speak of death is also, in a way, to project their own anguish.

As to active euthanasia ("an action which hastens the end"), a consensus appears to reject it, although one doctor in four over 50 years old thinks it a possibility.

Some doctors accept euthanasia in certain cases which I am going to cite to you. In each case, can you tell me if you agree with them?

Accept euthanasia — Exclusively at the patient's request	**Agree**	17%
	Disagree	22%
At the joint request of the patient and his family	**Agree**	13%
	Disagree	26%
At the request of the family alone, the patient being unconscious	**Agree**	17%
	Disagree	22%
At the doctor's initiative	**Agree**	26%
	Disagree	14%
Do not accept euthanasia under any circumstances		61%

Perceptible differences appear in comparison to the previous answers. There is a distance between "considered" euthanasia and the reality of concrete situations. However, the doctor, whatever his age, claims the initiative—if not the responsibility—for euthanasia.

The patient's request for an end to his suffering is most often taken into account with young doctors (21% at the request of the patient alone, 15% at the joint request of patient and family, 12% at the request of the family alone).

DEONTOLOGY:
The exceptions confirm the rule.

Would you wish for medical deontology (the science of moral obligation) to develop in the sense of giving physicians a greater freedom to shorten the suffering of a terminal patient?

	TOTAL	Age of Physicians: 35 years and less	36 to 50 years	Over 50 years
Yes	35%	33%	32%	40%
No	63%	64%	65%	60%
No Comment	2%	3%	3%	—

If one out of two doctors seems to accept the legitimacy of resorting to euthanasia, only one in three favors a deontological codification of more liberal attitudes. Practitioners seem to fear that such a method would constitute a constraint and make of euthanasia a "dogma" in contradiction with their continuous confrontations vis-a-vis individual situations.

In the French deontological code, no reference had been made to euthanasia until now. Le Conseil National de l'Ordre has just included in its project this draft of an article: "The doctor must strive to assuage suffering. He does not have the right, even in cases which he thinks hopeless, to deliberately hasten death." The general character of this text hardly seems adequate to meet the problem.

Praxis Triumphs Over Theory

The results of an opinion poll cannot replace the elements necessary for a solution. At the very most they allow us to establish a certain number of considerations. These may sometimes seem self-evident, but they do establish a break with "spontaneous sociology." To summarize:

- Euthanasia is for general practitioners a concrete problem, first of all, experienced professionally.
- With the advance of age, the position of family doctors appears less "idealized" and more in reference to their own condition as human beings. For them, to view death through the distorting prism of euthanasia is to consider their own death.
- Facing their inexperience, younger doctors appear more receptive to current thought expressed in the sense of an openness and a greater freedom [to consider and utilize alternatives]. In clinical situations, their position weakens somewhat.

Finally, our probe has an equal bearing on the nature of the physician's power. This power is not perceived by its holder as power in its liberal sense, but as a "power against" or a "counter-power" (perhaps meaning a power to equalize the power of technical medicine?). Yet, the euthanasia cases most favorably considered are those where the doctor decides alone, any intervention in the "singular conversation" being most often turned aside.

Coming Next Week

What do American family doctors think?

MEDICAL TRIBUNE's poll of American physicians was conducted in a manner identical to that of the French. The results show that the attitudes of U.S. doctors towards euthanasia differ markedly in at least one crucial respect.

Watch for it!

From La Tribune Médicale

One's Death

One looks at death as at the guillotine.

In considering it as a technical matter, one asks the doctor, to become a technician, to determine its precise instant. Yet biological data and medical progress often make death a development rather than a precise instant.

The doctor who endeavors to define death—a little in spite of himself and concerned above all with avoiding the wrath of justice and having to operate in enemy territory —can only fall back on his ethic or on his motto: "Respect for life."

Nevertheless, he will be reproached for breaking the moral contract that binds him to his patient, of not respecting the latter's free-will, of usurping his death. "Ill-willed speculations and gossip!" our practitioner will reply. A narrow margin lies between the breach of trust and the institution of legal proceedings. How does one bridge the gap?

Regulating euthanasia would be dangerous as well as illusory; the distinction between passive and active euthanasia is often subtle. The wish to allow a gentle death can also become, in a spirit of assistance, participation in the death of an individual.

The doctor would then regain his true vocation; faced with the death of his patient, he would assume the difficult responsibility he never ceased to exercise throughout the patient's life. To do that, he must have at his disposal a growing freedom, which will allow him choices other than the criminal justice system, voluntary homicide or non-assistance to a person in need. A less dogmatic ethic in evaluating individual situations, a wider range of judgment, left to the physician, would perhaps incite him to respect the values of the patient instead of being regularly "constrained" to impose his own values.

However, to give this freedom is to reinforce the power of the physician. Therefore, one must avoid judgments on death becoming the privilege of the medical world, in order to reintroduce humanity into technical medicine, each individual must be involved in a discussion on euthanasia.

One does not speak of death without speaking of one's own death. It must no longer be a reserved sphere, a taboo subject, since it gives to each existence its chance for life and to each life the shape of its destiny.

—JEAN-PIERRE DE KERRAOUL
EDITOR
La Tribune Médicale

Tribune Economic Analysis

Price Swings Upset Market In Metals

BY ELIOT JANEWAY
Consulting Economist

During 1976's upset of traditional metal market performance, copper has been glittering and gold has been the discarded workhorse put out to an exhausted pasture. Copper is commanding the market price premium that is theoretically reserved for gold as "pure money."

Experience has not supported the "store of value" or "pure money" claim put forth by the gold cultists.

Admittedly, the dollar devaluations were massive. The markdowns against the strong currencies averaged 33-40%. The markup in the price of gold, meanwhile, sent it clear up to $190 an ounce—a tripling of the old price.

The impact of the latest sterling devaluation reversed the historical patterns. When sterling was on the defensive at $2.20, copper was, too—at 620£ a ton. Sterling is still on the defensive at $1.85—more so now than then, despite its 20% drop. But the London price of copper has jumped to 900£ a ton, as of the beginning of last week. It is selling for more than 50% over the price it fetched when sterling was only 20% higher.

Moreover, the copper price jump has not run its course yet. The contrast between copper and gold is painful and pitiful. To be sure, gold was good for a triple while the going was good. The trouble now is that gold has since topped out and taken a decline of one-third. Alongside this, a 50% jump in copper looks pretty good, especially with gold going for almost nothing.

Ask Janeway

I am going to be 70 this year and plan to retire. I have an adequate amount of common stocks in municipals. If I do have some surplus money, how would you advise me to invest it?

I read your helpful column regularly in MEDICAL TRIBUNE.

Detroit MD

Try New York State tax exempts, including sub-divisions guaranteed by the State.

The brand name of New York has become a target of market panic. Consequently, New York State tax exempts have been beaten down to sell on nearly as high a yield basis as New York City tax exempts. But New York State's credit is being upgraded: witness its regained ability to peddle more paper. In your circumstances, an 8% tax free yield on a diminishing risk represents an opportunity. Limit your commitments to medium term.

Send your questions on finances, investments, taxes to Janeway, MEDICAL TRIBUNE, 880 Third Axenue, New York, N.Y. 10022.

Leukemia Remissions 100% on Chemotherapy

Continued from page 1

of 18 months, the American College of Physicians was told here by Dr. Lawrence H. Einhorn, Associate Professor of Medicine at the University.

Median survival, of 19 to 24 months, is almost double that of conventionally treated patients, he said.

The study is the first in the United States to use a regimen of prednisone, vincristine and daunomycine in adult patients with acute lymphocytic leukemia (ALL), and the findings are so "highly encouraging" that the trials will continue, the investigator said.

Although chemotherapy has produced "dramatic advances" in the treatment of childhood ALL, the results have not been paralleled in adults, Dr. Einhorn observed. Taking a clue, he said, from a preliminary study by Dr. George Mathé, French hematologist, the Indiana team added daunomycin to a prednisone-vincristine regimen in its trial. The lattter combination has been successfully employed in childhood ALL, while daunomycin has been effective as a single agent in adult acute leukemia.

The nine patients in the trial included eight men and one woman, aged 17 to 52, with a median initial WBC of 4,800. The patients received daunomycin three times weekly for three weeks, vincristine four times weekly for five weeks and prednisone daily for five weeks. Maintenance therapy consisted of methotrexate given weekly, and 6-mercaptopurine daily.

The regimen was repeated at six and 12 months, even if the patients were in remission.

"Complete remission was defined as a normal CBC and a normal cellular BM, with 0-5% lymphoblasts and fewer than 40% lymphocytic elements in the marrow, and no signs or symptoms of leukemia," Dr. Einhorn reported. "Duration of complete remission was defined as the interval from initial complete remission to relapse, either hematological or CNS with meningeal leukemia. Most patients were in complete remission within two weeks."

Toxicity Mild

Median duration of complete remission now stands at 18 months, with six relapses in the series, and three patients still in complete remission. Five deaths have occurred, all with progressive leukemia, at 13 to 24 months. Four patients are alive 11 to 24 months after the induction of therapy.

Two patients received CNS prophylaxis with 2,400 rads of craniospeinal irradiation but this was dropped in subsequent patients because of prolonged myelosuppression, Dr. Einhorn said. In an interview, he noted that the team has currently employed cranial irradiation alone, with intra-thecal methotrexate, only in patients over age 30, since there has been no evidence of meningeal leukemia in patients beyond that age.

Toxicity in the trial has been mild, Dr. Einhorn stated. There were no granulocytopenic infections, transfusion requirements were minimal, and such signs as neuromuscular toxicity, alopecia and Cushingoid facies, seen in all patients, were reversible.

In his interview, he said the team has now studied two additional patients and has achieved complete remissions in both with the combined regimen.

"Although we have treated only nine patients with our present regimen," he concluded in his formal report, "It is highly encouraging that the worst survival (13 months) was better than the median survival of our previous regimens."

Heart/Stroke Deaths Linked To Low Level Selenium Intake

Continued from page 1

centrations of each state's forage crops with the death rates from high blood pressure related diseases in the 55-64 year old age group, the investigators found that in "selenium-rich" states, such as Texas, Oklahoma, Arizona, Colorado, Louisiana, Utah, Alabama, Nebraska and Kansas, the death rate is much below the national average (67% below in Colorado Springs, 53% below the average in Austin, Texas.) In "selenium-poor" states, such as Connecticut, Illinois, Ohio, Oregon, Massachusetts, New York, Pennsylvania, Indiana and Delaware, the heart disease death rate is as much as 300% higher than it is in the high selenium states.

The Cleveland Clinic study was an outgrowth of earlier studies carried out elsewhere which showed that animals raised on low selenium diets developed heart abnormalities, while other work indicated that selenium in the proper amounts reduced angina. It has been also known that people who live in low selenium states have lower levels of selenium in their blood than residents of selenium-rich states, Dr. Shamberger said.

Role Unknown

Although selenium is known to act as an antioxidant in the body, reducing damage to all types of body tissue by oxygen, its role in lowering the heart disease death rate is still not understood, the Cleveland biochemist admitted. Neither is it known whether the body picks up most of its selenium content from food and water, or through inhalation from the atmosphere, as occurs with lead.

"Our research suggests that selenium supplements in the diets of people in selenium-poor areas would be beneficial. However, the material is not available commercially in a form suitable for human consumption. And, selenium would be dangerous if taken in substantial amounts," he cautioned.

Another survey presented at the FASEB meeting by Christine S. Wilson, Ph.D., a nutritionist at the University of California in San Francisco, links the low breast cancer rate found in Asian women to the high selenium content of the fish and grain that composes much of their diet.

In comparing the nutrient content of an average nonwestern diet supplying 2500 calories to that of a typical American diet providing the same number of calories, Dr. Wilson found that the Asian diets contained from two to four times as much selenium as the western diets did. Also, the amounts of easily oxidized polyunsaturated fatty acids in the Asian diets ranged from 7.5 to 8.7 grams, compared to from 10 to 30 grams in the western diet.

Dr. Wilson speculated that it is the combination of high intake of selenium and low intake of unsaturated fat that may explain the low breast cancer rates in Asian women. Selenium is a component of the enzyme glutathione.

Continued on page 17

Radioactive Iodine Implants Favored in Prostatic Cancer

Continued from page 3

low emission rate. This is particularly useful in treating a slow-growing disease like cancer of the prostate, notes Dr. Reddi.

"All nine of our patients are surviving and none has reported any complications because of the I-125 implant," says Dr. Kandzari.

In contrast, "about 20% of patients having radical surgery will have urinary incontinence," he says. "About 90 to 100% will be impotent. Patients electing interstitial radiation can have a normal sex life. And if the treatment should fail, the patient still has the option of going for external radiation."

Patients are hospitalized eight days and postoperative recovery time and rehabilitation are shortened, he adds.

Dr. Reddi points out that unlike external radiation which requires frequent treatments, implantation of radioactive iodine is a one-time procedure.

In addition, the side effects common to external cobalt radiation therapy—bladder and urinary problems, colitis, diarrhea, skin reactions, intestinal and rectal disturbances, are absent with the implantation technique, he says. The radiation extends not more than 1 cm. outside the gland, he explains.

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(guanethidine sulfate)

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> **WARNING (Esimil)**
> This fixed combination drug is not indicated for initial therapy of hypertension. Hypertension requires therapy titrated to the individual patient. If the fixed combination represents the dosage so determined, its use may be more convenient in patient management. The treatment of hypertension is not static, but must be reevaluated as conditions in each patient warrant.

INDICATIONS
Ismelin
Moderate and severe hypertension either alone or as an adjunct.
Esimil
Hypertension. (See box warning above.)
CONTRAINDICATIONS
Guanethidine: Known or suspected pheochromocytoma; hypersensitivity; frank congestive heart failure not due to hypertension; use of MAO inhibitors.
Hydrochlorothiazide: Anuria; hypersensitivity to this or other sulfonamide-derived drugs. The routine use of diuretics in an otherwise healthy pregnant woman with or without mild edema is contraindicated and possibly hazardous.
WARNINGS
Antihypertensives are potent drugs and can lead to disturbing and serious clinical problems. Physicians should be familiar with all drugs and their combinations before prescribing, and patients should be warned not to deviate from instructions.
Guanethidine

> Warn patients about the potential hazard of orthostatic hypotension, which can occur frequently and is most marked in the morning and is accentuated by hot weather, alcohol, or exercise. To help prevent fainting, warn patients to sit or lie down with onset of dizziness or weakness, which may be particularly bothersome during the initial period of dosage adjustment and with postural changes. The potential occurrence of these symptoms may require alteration of previous daily activity. Caution patients to avoid sudden or prolonged standing or exercise while taking the drug.

Concurrent use with rauwolfia derivatives may cause excessive postural hypotension, bradycardia, and mental depression.
If possible, withdraw therapy 2 weeks prior to surgery to reduce the possibility of vascular collapse and cardiac arrest during anesthesia. If emergency surgery is indicated, administer preanesthetic and anesthetic agents cautiously in reduced dosage and have oxygen, atropine, vasopressors, and IV solutions ready for immediate use to treat vascular collapse. Vasopressors should be used with extreme caution in patients on guanethidine because of the possibility of augmented response and the greater propensity for cardiac arrhythmias.
Dosage requirements may be reduced in presence of fever. Exercise special care when treating patients with a history of bronchial asthma, since their condition may be aggravated.
Hydrochlorothiazide
Use with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.
Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte imbalance may precipitate hepatic coma.
Thiazides may be additive or potentiative of the action of other antihypertensive drugs. Potentiation occurs with ganglionic or peripheral adrenergic blocking drugs.
Sensitivity reactions are more likely to occur in patients with a history of allergy or bronchial asthma.
The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.
Usage in Pregnancy
Guanethidine: The safety of guanethidine for use in pregnancy has not been established; therefore, this drug should be used in pregnant patients only when, in the judgment of the physician, its use is deemed essential to the welfare of the patient.
Hydrochlorothiazide: Usage of thiazides in women of childbearing age requires that the potential benefits of the drug be weighed against its possible hazards to the fetus. These hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.
Nursing Mothers
Thiazides cross the placental barrier and appear in cord blood and breast milk.
PRECAUTIONS
Guanethidine: The effects of guanethidine are cumulative over long periods; initial dose should be small and increased gradually in small increments. Use very cautiously in hypertensives with: renal disease and nitrogen retention or rising BUN levels; coronary disease with insufficiency or recent myocardial infarction; cerebral vascular disease, especially with encephalopathy. Do not give guanethidine to patients with severe cardiac failure except with extreme caution.
In incipient cardiac decompensation weight gain or edema may be averted by the administration of a thiazide. Remember that both digitalis and guanethidine slow the heart rate.
Peptic ulcers or other chronic disorders may be aggravated by a relative increase in parasympathetic tone.
Amphetamine-like compounds, stimulants (eg, ephedrine, methylphenidate), tricyclic antidepressants (eg, amitriptyline, imipramine, desipramine) and other psychopharmacologic agents (eg, phenothiazines and related compounds), and oral contraceptives may reduce the hypotensive effect of guanethidine. Discontinue MAO inhibitors for at least one week before starting guanethidine.
Hydrochlorothiazide: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. Observe patients for clinical signs of fluid or electrolyte imbalance (hyponatremia, hypochloremic alkalosis, and hypokalemia). Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Warning signs are dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbance such as nausea or vomiting.
Hypokalemia may develop with thiazides as with any other potent diuretic, especially during brisk diuresis, when severe cirrhosis is present, or during concomitant administration of steroids or ACTH.
Interference with adequate oral intake of electrolytes will also contribute to hypokalemia. Digitalis therapy may exaggerate metabolic effects of hypokalemia especially with reference to myocardial activity.
Any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease). Dilutional hyponatremia may occur in edematous patients [illegible] weather; appropriate therapy is [illegible] restriction rather than administ[illegible] salt, except in rare instances [illegible] the hyponatremia is life-threat[illegible]. In actual salt depletion, appro[illegible] replacement is the therapy of [illegible].
[illegible] elevations in plasma cal[illegible] may occur in patients receiving [illegible], particularly in those with [illegible]parathyroidism. Pathological [illegible] in the parathyroid gland have [illegible] reported in a few patients on [illegible] thiazide therapy.
[illegible] may occur or frank gout may be precipitated in certain patients. Insulin requirements in diabetic patients may be increased, decreased, or unchanged. Latent diabetes may become manifest during thiazide administration.
Thiazide drugs may increase the responsiveness to tubocurarine. The antihypertensive effects of the drug may be enhanced in the post-sympathectomy patient. Thiazides may decrease arterial responsiveness to norepinephrine. This is not sufficient to preclude effectiveness of the pressor agent for therapeutic use.
If nitrogen retention indicates onset of progressive renal impairment, consider withholding or discontinuing diuretic therapy.
Thiazides may decrease serum PBI levels without signs of thyroid disturbance.
ADVERSE REACTIONS
Guanethidine: *Frequent reactions due to sympathetic blockade*—dizziness, weakness, lassitude, syncope. *Frequent reactions due to unopposed parasympathetic activity*—bradycardia, increase in bowel movements, diarrhea (may be severe and necessitate discontinuance of the drug).
Other common reactions—inhibition of ejaculation, fluid retention, edema, congestive heart failure. *Other less common reactions*—dyspnea, fatigue, nausea, vomiting, nocturia, urinary incontinence, dermatitis, scalp hair loss, dry mouth, rise in BUN, ptosis of the lids, blurring of vision, parotid tenderness, myalgia, muscle tremor, mental depression, chest pains (angina), chest paresthesias, nasal congestion, weight gain, and asthma in susceptible individuals. Although a causal relationship has not been established, a few instances of anemia, thrombocytopenia and leukopenia have been reported.
Hydrochlorothiazide: *Gastrointestinal*—anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation, jaundice (intrahepatic cholestatic), pancreatitis. *Central Nervous System*—dizziness, vertigo.

(Brief prescribing information continued on next page)

One Man... and Medicine

ARTHUR M. SACKLER, M.D.
International Publisher, Medical Tribune

A Needed Book Unpublished

TWO YEARS AGO *I was asked to write a foreword to a review of the literature on sterilization, composed by Bernard L. Rosenfeld, M.D., Ph.D., in conjunction with Ralph Nader's Health Research Group. The book was to have been released through the Health Research Group. Hopefully, it will be, but in accord with the author's suggestion that we be "free to use any of this information for any purpose" and in the hope that publication of this Foreword may advance or make possible the publication of the book itself, it is presented herewith.*

The right to have a child—or not have a child—is now recognized as a basic human right. How to exercise this right is of vital importance to every man and woman. A proper decision is dependent upon an informed understanding of the physical and emotional price as well as the social implications of available measures for conception control. This book should help each man and woman to come to a sounder decision as to family planning with happier consequences, free from regrets and as free as possible from physical or psychologic hazard.

What Are the Risks?

This book is exciting, interesting and informative. Vital issues are addressed simply and directly, sometimes pungently but always with an effort to achieve a balanced presentation of judgments and views. What are the risks as well as advantages of sterilization for a woman? For a man? What are the regrets and what are the complications? At what age and under what conditions should sterilization *not* be considered? How safe is The Pill? What are its risks, its advantages? How does The Pill increase the danger of gonorrheal infection after exposure? What about the IUD (*Intra Uterine Devices*)? This book provides the basic information that every woman, and every man, should have if they are to have a happy result from conception control with modern technology.

It is my hope that physicians will prescribe this book routinely as part of their consultation before deciding together with their patients, what should be the individual preferred procedure for conception control. The closest consultation between the patients and their personal physicians and based upon the type of informed judgment this book makes possible—these two elements can make for a medically sound and personally gratifying selection of contraceptive method. It would be Utopian to expect each individual physician to be able to take the hours needed and each individual patient to be able to retain and comprehend from a single consultation the implications of all the facts made available in these pages. This book can make the difference for millions between fulfillment and regret, and even for a few between life and death.

Decision of the Individual

Interest in population size has shown an historic shift. In the past, families needed numbers to assure continuity, and societies needed larger populations for survival and development. Now, the need in most countries is for a stabilized population. The spacing of childbearing was advocated first for the protection of the mother, then to assure a balanced, healthy family. Population restriction is now being pushed primarily in the interest of society and mankind at large. It is my opinion that the decision of the individual must, first and foremost, accord with her or his own needs. The slogans for ZPG (Zero Population Growth), the ecology crisis, the crisis about the shortages of raw material must not obscure or distort the fact that a decision on family size must be a personal decision consistent with the best interests of the individual and with the health and happiness of the basic unit out of which all societies are built—the family.

No sensitive individual wants more human beings crushed in a world of misery, short in food, and polluted by poisons. There must be equal sensitivity to the fact that for the poor farmer in India, the survival of some members of the family represent not only an immediate measure of social security but some assurance for posterity. Each sensitive individual must recognize that those nations that speak loudest of the "horrors of the population explosion" and the shortages of land, food and energy are precisely those that are most profligate in the consumption of these essentials. In this context, it has been said that "one extra American is a worse disaster for the world than a dozen extra Asians."

Need for Balanced Approach

One must recognize that the reduction in population pressures and the preservation of all species are worthwhile goals. One can most respect the advocacy of enthusiasts who address not only the technology of conception control but also measures to reduce the waste and pollution, to raise food output and living standards and to assure a more fair and equitable access to the raw materials, the necessities and comforts of this planet for all individuals. An unbalanced approach does not properly serve but may impair the valid objectives we have discussed. Conception control technologies lifted out of context of the needs of the individual—physical and psychic, social and economic—can only fail. It has already led to charges of genocide and repression, to fears of its use for political purposes against certain racial groups, against disabled or disadvantaged individuals such as the unwanted, undesirable or unpopular. History bears witness to the fact that this is not a hypothetical possibility.

The issues which Dr. Rosenfeld addresses confront every woman of childbearing age, every man in the reproductive phase of his life, and in fact every thinking person. Reproduction remains, as it always will, a highly personal matter and its control has its first and fullest impact on the primary unit of society—husband and wife, man and woman. Contraceptive technology can be effective only in the context of societies which will assure their people of jobs and food, of housing and health. This book can help in its proper use.

EPIGRAMS—Clinical and Otherwise

Man should go out of this world as he came in—chiefly on milk.

Sir William Osler
(1849-1919)
in *Aphorisms from His Bedside Teachings*

Medicine on Stamps

Queen Elizabeth of Belgium

Queen Elizabeth of Belgium (1876-1965) was born in Bavaria, the daughter of Duke Karl Theodor, a practicing ophthalmologist. She studied nursing and then medicine, receiving an M.D. from Leipzig in 1900. To date she is the only member of royalty to receive an M.D. degree through study. Later she received honorary medical degrees from Brussels, Liege and Lille. During World War I she tended the wounded, and in War II she worked with the Red Cross. The above stamp portrays her assisting at an operation performed by Drs. Debaissieux and Depage, the only stamp that portrays her in a medical capacity.

Text: Dr. Joseph Kler
Stamp: Minkus Publications, Inc., New York

Heart/Stroke Deaths Tied to Low Level Selenium Intake

Continued from page 13

peroxidase, which prevents the oxidation of unsaturated fats to peroxides and free radicals, both of which are suspected of initiating various forms of cancer, she said. Reflecting Dr. Wilson's conclusions, Dr. Shamberger said that other surveys carried out at Cleveland Clinic indicate that high selenium levels in certain areas appear to reduce the frequency of deaths from cancer of the colon.

In another FASEB report, Dr. Leslie M. Klevay suggested that the 44% rise in coronary heart disease in the United States over the last 15 years might be tied to a corresponding decline of copper in our food supply. For example, he noted that a comparison of food analyses made by the United States Department of Agriculture in 1942 and 1966 shows that 30 of 47 fresh foods contained less copper than they did in 1942.

'Cause for Concern'

"The decrease in copper concentration is a cause for concern," says Dr. Klevay, explaining that recent USDA dietary analyses have shown that many people in this country are eating diets containing less than 2 milligrams of copper a day, the level generally believed to be required for adequate adult nutrition. Dr. Klevay is medical officer of the USDA's Agricultural Research Service Human Nutrition Laboratory on Grand Forks, North Dakota.

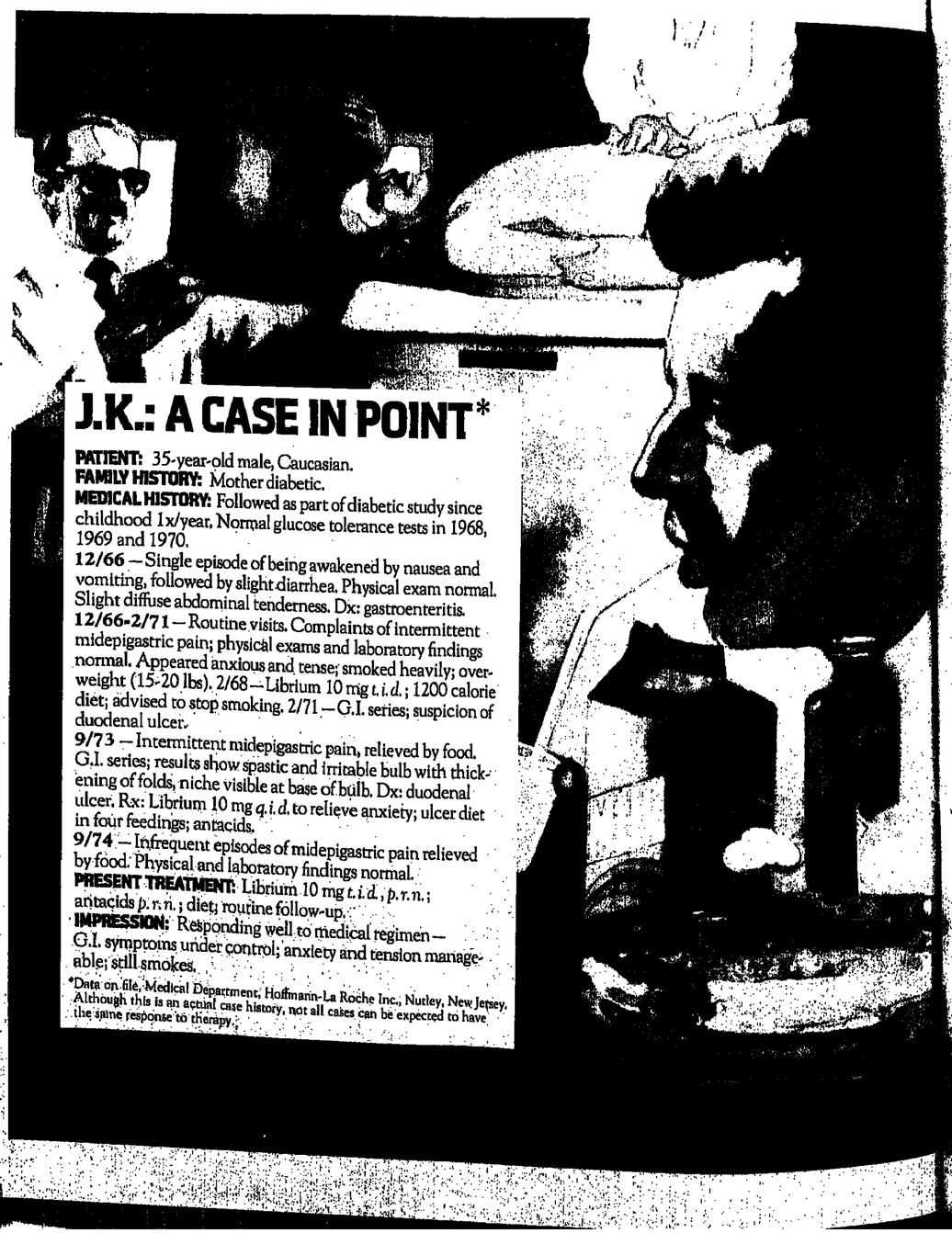
He said that he is also concerned that the low levels of copper are creating a dietary imbalance between that metal and zinc, resulting in a proportionate increase in zinc. Previous research with laboratory rats has shown that diets that are high in zinc relative to copper increase cholesterol levels in the blood. Findings from recent studies show that a dietary imbalance of zinc and copper also may affect cholesterol levels in human blood.

Many paradoxical observations about the etiology of coronary heart disease can be reconciled with the hypothesis that abnormally high zinc-to-copper ratios are responsible, according to the USDA scientist. For example, the previously reported beneficial effects of hard water on the incidence of heart disease could mean that calcium in the hard water increases the absorption of zinc from the intestines, as well as moving more zinc from the liver to bone. In either case, the zinc-to-copper ratio is decreased in tissue responsible for cholesterol production.

Gerontologists to Be On Nationwide TV

Leading physicians in the field of gerontology will appear on a television show, "What Do You Want To Be When You Grow Old?," that will be broadcast in various sections of the country, beginning in the Southwest the week of May 24. Dr. Ewald W. Busse, president of the American Geriatrics Society and founder of the Duke University Center for the Study of Aging and Human Development, and Robert N. Butler, research psychiatrist and gerontologist at the Washington School of Psychiatry and Director of the new National Institute of Aging, will be interviewed on various aspects of the problems of aging.

LIBRIUM® AT WORK: (chlordiazepoxide HCl)



J.K.: A CASE IN POINT*

PATIENT: 35-year-old male, Caucasian.
FAMILY HISTORY: Mother diabetic.
MEDICAL HISTORY: Followed as part of diabetic study since childhood 1x/year. Normal glucose tolerance tests in 1968, 1969 and 1970.
12/66—Single episode of being awakened by nausea and vomiting, followed by slight diarrhea. Physical exam normal. Slight diffuse abdominal tenderness. Dx: gastroenteritis.
12/66-2/71—Routine visits. Complaints of intermittent midepigastric pain; physical exams and laboratory findings normal. Appeared anxious and tense; smoked heavily; overweight (15-20 lbs). 2/68—Librium 10 mg *t.i.d.*; 1200 calorie diet; advised to stop smoking. 2/71—G.I. series; suspicion of duodenal ulcer.
9/73—Intermittent midepigastric pain, relieved by food. G.I. series; results show spastic and irritable bulb with thickening of folds, niche visible at base of bulb. Dx: duodenal ulcer. Rx: Librium 10 mg *q.i.d.* to relieve anxiety; ulcer diet in four feedings; antacids.
9/74—Infrequent episodes of midepigastric pain relieved by food. Physical and laboratory findings normal.
PRESENT TREATMENT: Librium 10 mg *t.i.d.*, *p.r.n.*; antacids *p.r.n.*; diet; routine follow-up.
IMPRESSION: Responding well to medical regimen—G.I. symptoms under control; anxiety and tension manageable; still smokes.

*Data on file, Medical Department, Hoffmann-La Roche Inc., Nutley, New Jersey. Although this is an actual case history, not all cases can be expected to have the same response to therapy.

IN THE ANXIOUS PATIENT WITH ORGANIC GASTROINTESTINAL DISEASE

CLINICAL ANXIETY AND THE G.I. PATIENT

After the ulcer patient's acute episode is under control, your counseling and reassurance about the status of the ulcer are often enough to allay anxiety. In some patients, however, excessive anxiety and emotional tension may interfere with medical management. When this occurs, Librium (chlordiazepoxide HCl) may be a beneficial adjunct.

Librium offers a high degree of antianxiety effectiveness, with relatively few side effects, for the ulcer patient. In addition to a long clinical record of prompt and effective action, Librium has an established safety record and an excellent record of patient acceptance. In proper dosage, it usually helps calm the overanxious patient without interfering with mental acuity or general performance. However, as with all CNS-acting drugs, patients should be cautioned against hazardous activities requiring complete mental alertness. Librium is often used concomitantly with certain specific medications of other classes of drugs, *e.g.*, anticholinergics and antacids. Of course, Librium therapy should be discontinued after anxiety has been reduced to tolerable levels.

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Relief of anxiety and tension occurring alone or accompanying various disease states.

Contraindications: Patients with known hypersensitivity to the drug.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. As with all CNS-acting drugs, caution patients against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Though physical and psychological dependence have rarely been reported on recommended doses, use caution in administering to addiction-prone individuals or those who might increase dosage; withdrawal symptoms (including convulsions), following discontinuation of the drug and similar to those seen with barbiturates, have been reported. Use of any drug in pregnancy, lactation or in women of childbearing age requires that its potential benefits be weighed against its possible hazards.

Precautions: In the elderly and debilitated, and in children over six, limit to smallest effective dosage (initially 10 mg or less per day) to preclude ataxia or oversedation, increasing gradually as needed and tolerated. Not recommended in children under six. Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider individual pharmacologic effects, particularly in use of potentiating drugs such as MAO inhibitors and phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions (e.g., excitement, stimulation and acute rage) have been reported in psychiatric patients, and hyperactive aggressive children. Employ usual precautions in treatment of anxiety states with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation have been reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship has not been established clinically.

Adverse Reactions: Drowsiness, ataxia and confusion may occur, especially in the elderly and debilitated. These are reversible in most instances by proper dosage adjustment, but are also occasionally observed at the lower dosage ranges. In a few instances syncope has been reported. Also encountered are isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent and generally controlled with dosage reduction; changes in EEG patterns (low-voltage fast activity) may appear during and after treatment; blood dyscrasias (including agranulocytosis), jaundice and hepatic dysfunction have been reported occasionally, making periodic blood counts and liver function tests advisable during protracted therapy.

Supplied: Librium® Capsules containing 5 mg, 10 mg or 25 mg chlordiazepoxide HCl. Libritabs® Tablets containing 5 mg, 10 mg or 25 mg chlordiazepoxide.

ROCHE

Roche Laboratories
Division of Hoffmann-La Roche Inc.
Nutley, New Jersey 07110

WHEN CLINICAL ANXIETY INTERFERES WITH PATIENT MANAGEMENT

LIBRIUM® CV
chlordiazepoxide HCl/Roche
5 mg, 10 mg, 25 mg capsules
FOR ALL THE RIGHT REASONS

Ultrasound Suppresses Spermatogenesis

Continued from page 1

patients found the treatments pleasurable.

Dr. Fahim reported on five men who were successfully treated with a dosage of 1,100,000 cycles per second for two 10 minute periods, which he estimated would produce azospermia for one to two years.

All patients had carcinoma of the prostate and were scheduled for orchiectomy, but none had received steroids.

During treatment, the heat in the testes never rose above 39°C.

Testicular biopsies taken three weeks after treatment showed azospermia in all patients.

Treatment was given in a special chair designed to hold the patient's testes in a cup filled with water as a coupling agent for the vibrations from an ultrasonic transducer.

Dr. Fahim feels that the results are promising and after studying several more patients he plans to offer the treatment on a limited basis to men who request vasotony.

Wide Application

In an interview, he said that he had explored the use of hot water, infrared and microwaves before using ultrasound as an electronic means of heat production and vibration.

He foresees wide application of the method in countries in the Middle East and Europe, where he says religious beliefs and male chauvanism make vasectomy unacceptable.

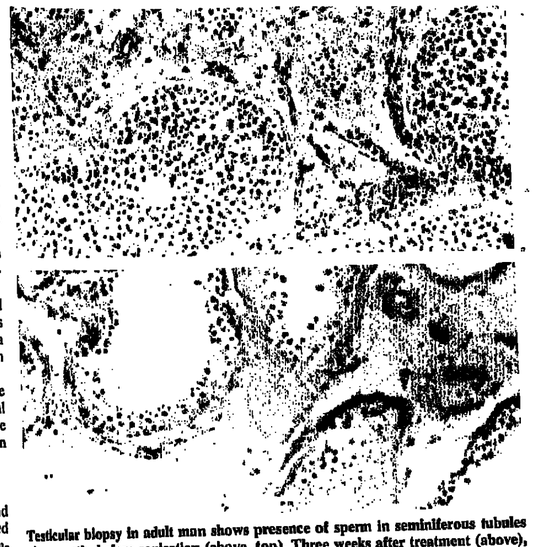
"I hope that the ultrasonic chair we designed can become like a Turkish bath.

"Men could go to a health club-like clinic and take treatments simply by sitting in a chair, which would be pleasant and acceptable."

But several questions must be resolved before the method is put into practice.

Whether the technique is completely reversible is unknown and will require much additional research, says Dr. Fahim.

It may also be possible to use the method more than once to suppress spermatogenesis.



Testicular biopsy in adult man shows presence of sperm in seminiferous tubules nine months before sonication (above, top). Three weeks after treatment (above), germs cells have lost ability to differentinte and produce sperm.

But the most pressing questions are the optimum dosage needed to achieve azospermia and how long does the effect last.

According to Dr. Fahim the effectiveness of ultrasound in suppressing spermatogenesis depends on the size of the testes, the energy used per unit area, the frequency of treatment, the size of the cup, the position of the testes in the cup and the age of the patient.

While dosage schedules have been worked out for rats, cats, dogs and monkeys, most of these data are not applicable to humans.

Dr. Fahim emphasized that he waited for more than three years to get five men who were suitable candidates for treatment.

The mechanism through which ultrasound suppresses spermatogenesis is unknown, although Dr. Fahim believes there is a combined effect of generated heat and mechanical vibration.

He hypothesizes that these cause an ion exchange between the fluid in the seminiferous tubules and the rete testes so that the general epithelium loses its ability to differentiate and produce sperm.

Libido Increased

One interesting phenomenon of ultrasound is that it affects the seminiferous tubules but not the hormone-producing Leydig cells. Consequently, there is an increase in libido after treatment because of the continued manufacture of hormones no longer needed for spermatogenesis.

No significant difference in blood testosterone was noted after treatment.

During his studies Dr. Fahim found a new application for the ultrasonic chair. Since ultrasound increases cell permeability, medication can be placed in the cup to speed up treatment of prostatitis and testicular ailments.

His coworkers are Drs. Joseph Montie, Ian M. Thompson and D. G. Hall.

Technology Assists Medical Students

Videocassette and playback equipment are now used to supplement classroom instruction of medical students at the University of Kansas Medical Center, Kansas City. Multimedia Center also uses computers, films, audiotapes, charts and anatomy models to provide individualized learning.

Mutagenic Flame Retardant

Medical Tribune Report

NEW YORK—Tris (2,3-dibromopropyl) phosphate (TBPP)—"by far the most important flame-retardant compound used in man-made fibers"—causes genetic alterations in microbial bioassay systems, according to Dr. Herbert S. Rosenkranz, Professor and Chairman, department of microbiology, New York Medical College. As an environmental mutagen with the potential of inducing cancer, continued widespread use of TBPP ought to be evaluated, especially since nonmutagenic flame retardants are available, Dr. Rosenkranz said.

Clinical Trials

By Oldden

IMMATERIA MEDICA

The Passing of El Macho

We recently called Barnes Hospital, a part of Washington University School of Medicine in St. Louis, in hopes of doing an interview with El Macho, its famous rooster—and learned that that great and aged bird is no longer among the living. We won't go into the details of his passing, but we think we ought to tell you that this irascible bird got his name, El Macho, which means "the man", from Argentine-born Dr. Eduardo Slatopolsky, of the medical center's dialysis unit.

What made El Macho famous was his unique ability to produce an antibody that permitted measurement of parathyroid levels in kidney disease and dialysis patients. These measurements aided in the prevention of calcium deficiencies. El Macho's antibody was so sensitive that it could measure one-millionth of a milligram of parathyroid hormone in the blood. Shipments of his antibody were sent to Europe, Latin America and most of the United States.

Once TV news and science writers discovered El Macho, Dr. Slatopolsky was tied up for hours, holding a ferocious, annoyed, wing-flapping El Macho for camera crews who wanted him to do some early morning crowing for the late news show.

Finally, Dr. Slatopolsky told Peter Gorner of the Chicago Tribune, "Enough is enough. It's getting worse than Watergate. No more interviews. Other researchers will think I'm after publicity, that maybe I'm selling a commercial product. I don't want that."

And now El Macho is gone, quietly, without publicity. His serum, which was regularly drawn and frozen for some time before his demise, will continue to be available for many years. But as they say around the hen house, he's going to be hard to replace.

Medical Monkey Business

There's a monkey shortage in your future. The number imported has dropped from 126,857 in 1968 to 69,548 in 1973—and now India, Thailand, Peru, Colombia, and Brazil have cut their exports...